Uniquely shaped cardiovascular stents enhance the pressure generation of intravascular blood pumps

Amy L. Throckmorton, PhD,[a] James P. Carr, BS,[a] William B. Moskowitz, MD,[b] James J. Gangemi, MD,[c] Christopher M. Haggerty, BS,[d] and Ajit P. Yoganathan, PhD[d]

Objective: Advances in the geometric design of blood-contacting components are critically important as the use of minimally invasive, intravascular blood pumps becomes more pervasive in the treatment of adult and pediatric patients with congestive heart failure. The present study reports on the evaluation of uniquely shaped filaments and diffuser blades in the development of a protective stent for an intravascular cavopulmonary assist device for patients with a single ventricle.

Methods: We performed numeric modeling, hydraulic testing of 11 stents with an axial flow blood pump, and blood bag experiments (n = 6) of the top-performing stent geometries to measure the levels of hemolysis. A direct comparison using statistical analyses, including regression analysis and analysis of variance, was completed.

Results: The stent geometry with straight filaments and diffuser blades that extended to the vessel wall outperformed all other stent configurations. The pump with this particular stent was able to generate pressures of 2 to 32 mm Hg for flow rates of 0.5 to 4 L/min at 5000 to 7000 RPM. A comparison of the experimental performance data to the numeric predictions demonstrated an excellent agreement within 16%. The addition of diffuser blades to the stent reduced the flow vorticity at the pump outlet. The average and maximum normalized index of hemolysis level was 0.0056 g/100 L and 0.0064 g/100 L, respectively.

Conclusions: The specialized design of the stents, which protect the vessel wall from the rotating components of the pump, proved to be advantageous by further augmenting the pressure generation of the pump, reducing the flow vorticity at the pump outlet, and enhancing flow control. (J Thorac Cardiovasc Surg 2012;144:704-9)

Thousands of blood pumps currently provide circulatory support to patients worldwide, and the frequency of their use has been increasing owing to design innovation in the early 1980s and an increase in knowledge regarding ideal patient selection and operational limitations. The field of artificial blood pumps has benefited from technological advances that have enabled a paradigm shift from the use of bulky, pulsatile blood pumps to smaller, continuous flow pumps, with much success. The latest technology of rotary blood pumps incorporates design innovation related mostly to the power drive systems, such as the incorporation of magnetic bearings.[1] As the use of blood pumps becomes more pervasive in the treatment of those patients with congestive heart failure, critical advances in all design features to address the known limitations through the integration of novel technologies become even more urgent.

During the past decade, medical intervention and technology development have shifted to the implementation of minimally invasive procedures and the percutaneous deployment of devices. All percutaneously inserted blood pumps use standard impeller geometries and protective stent designs. For example, the Abiomed Impella pump, which is used to treat patients with cardiogenic shock, has helically shaped impeller blades and a standard stent with straight filaments.[2] The protective cage or stent around current intravascular pumps is not designed to maximize energy transfer but, rather, to minimize manufacturing effort. To improve flow control and energy transfer, we evaluated the inclusion of a uniquely shaped protective cage to advance the current state-of-the-art and create a new intravascular blood pump as a therapeutic option for patients with ailing single-ventricle physiology. This approach can be more broadly applied to the development of all intravascular blood pumps to support adult or pediatric patients with heart failure.

The initial protective stent design around our axial flow blood pump incorporated straight filaments similar to that of existing technology.[3-6] The rotation of the helically shaped impeller blades leads to a torque in the blood and, thus, vorticity in the flow exiting the pump. During the first phase of the present study, we sought to incorporate stationary diffuser blades onto the protective stent to

From the Department of Mechanical Engineering,[a] Virginia Commonwealth University School of Engineering, Richmond, Va; Division of Pediatric Cardiology,[b] Virginia Commonwealth University Medical College of Virginia, Richmond, Va; Division of Thoracic and Cardiovascular Surgery,[c] University of Virginia School of Medicine, Charlottesville, Va; and Wallace H. Coulter School of Biomedical Engineering,[d] Georgia Institute of Technology and Emory University, Atlanta, Ga.

Financial support provided by the American Heart Association Beginning Grant-in-Aid (grant 0865320E) and the National Science Foundation (grant EEC-0823383).
Disclosures: Authors have nothing to disclose with regard to commercial support.
Received for publication Aug 28, 2011; accepted for publication Dec 14, 2011; available ahead of print Feb 17, 2012.

Address for reprints: Amy L. Throckmorton, PhD, Department of Mechanical Engineering, Virginia Commonwealth University School of Engineering, 401 West Main Street, Room E3221, PO Box 843015, Richmond, VA 23284 (E-mail: althrock@vcu.edu).

0022-5223/$36.00

doi:10.1016/j.jtcvs.2011.12.061

Abbreviations and Acronyms
CFD = computational fluid dynamics
pfHb = plasma free hemoglobin

remove the rotational torque, straighten the flow, and improve pressure generation across the pump. We performed a numeric analysis on the protective stent without and with diffuser blades. We also examined the effect of the number of diffuser blades on pressure generation. Moreover, the shear stress levels and cross-sectional flow vorticity along the axial locations of the pump models from the diffuser to the outflow region were computationally analyzed. Two prototypes were manufactured (ie, a cage without diffuser blades and cage having a 4-bladed diffuser) for hydraulic testing. The second phase of the present study involved the design of uniquely twisted protective stent geometries to further augment pressure generation across the pump. Nine additional prototypes of stent geometries were manufactured for hydraulic evaluation, quantitative comparison, and hemolysis testing.

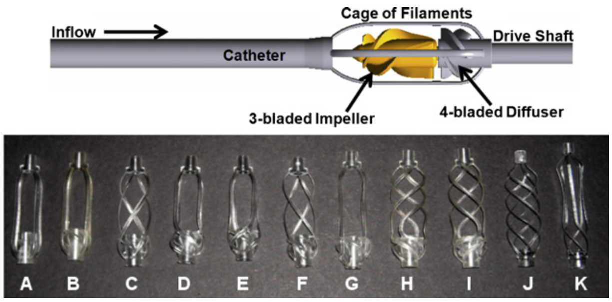


FIGURE 1. Axial flow blood pump and all stent configurations that were hydraulically evaluated. A, Straight filaments without stationary diffuser blades; B, straight filaments with diffuser blades; C, fully twisted filaments with impeller blades and against diffuser blades; D, partial twisted filaments in the direction of the diffuser blades; E, partial twisted filaments against the diffuser blades; F, fully twisted filaments against the impeller blades and with the diffuser blades; G, straight filaments with the diffuser blades extending the full diameter into the vessel; H, filament twist with the impeller blades and diffuser blades; I, filament twist against the impeller blades and against the diffuser blades; J, fully twisted filaments with no diffuser blades; K, partial twist in the filaments and no diffuser blades. In all configurations, except for G, there is a 1.5-mm clearance between the filaments and diffuser blade tip surface. Configuration G has the diffuser blades extended out to the filaments and into the vessel.

METHODS

Blood Pump Conceptual Design

Figure 1 illustrates the conceptual design of the axial flow blood pump. The cavopulmonary assist device was designed for percutaneous positioning in the inferior vena cava or extracardiac conduit of single ventricle physiology. The outer protective stent has radially arranged filaments that serve as touchdown surfaces for the rotating components. The pump consists of an impeller with 3 uniquely designed blades having characteristic angles that are appropriate to achieve the desired operating range. Pump rotation is induced through a drive cable–fluid seal combination with a port to supply a dextrose solution as lubrication between cable and polyurethane outer cover and to flush the fluid seal of any accumulated blood elements. For the present study, we used a shaft-driven configuration for each of the models, hydraulic experiments, and hemolysis studies. The target design for this pump was to generate flow rates of 0.5 to 4 L/min with pressure increases of 2 to 25 mm Hg for 3000 to 8000 RPM. It is designed to provide 4 weeks of temporary mechanical circulatory support with replacement possible for prolonged support.[3-6]

Computational Fluid Dynamics of Stent with Diffuser Blades

Similar to previously executed computational studies,[3-7] we used ANSYS software CFX, version 12.1 (ANSYS, Canonsburg, Pa) to simulate flow through the pump models with the diffuser designs. The present study included the creation of 5 pump models with the following number of diffuser blades: 0, 2, 3, 4, and 5. Each computational fluid dynamics (CFD) model was constructed of approximately 8.75 million elements. The program solves the Reynolds-Averaged Navier-Stokes equations, coupled with the selection of an appropriate turbulence model, to achieve closure when modeling turbulent flow conditions. The k-ε turbulence model was selected according to the acceptable numeric correlation to the experimentally measured performance in geometrically similar prototypes of previous work.[3-7] Hydraulic performance curves were obtained for a wide flow range for rotational speeds from 5000 to 7000 RPM. We examined the vorticity at the axial locations along the outlet region of the pump to assess flow straightening due to the diffuser blades. We also examined the shear stress levels in the fluid domain.[8] Furthermore, a grid density and convergence study were completed for grid quality assurance.[9] Boundary conditions and fluid properties were specified according to previous studies.[3,6,7]

Prototype Manufacturing

Using SolidWorks (Concord, Mass) to generate the models, we designed 11 protective stents of various configurations, including with or without diffuser blades, and having twisted or straight filaments. These filament and diffuser designs were devised according to the computationally predicted rotational component of the blood flow exiting the impeller region of the pump. All the prototypes were manufactured by a rapid prototyping using a watershed resin material. Figure 1 illustrates the stent configurations.

Hydraulic Performance Evaluation and Hemolysis Testing

A hydraulic flow loop was previously designed and constructed for the performance testing of the blood pump prototypes with a protective stent of filaments. Details of the test loop and the experimental protocol have been previously reported.[4,5,7] A water and glycerin solution (60%/40%) was used as the fluid medium. The 3-bladed impeller was rotated at 5000, 6000, and 7000 RPM. This impeller was used to evaluate the performance of the stent prototypes. For each RPM, more than 30 different flow rates were examined, and a corresponding pressure increase across the prototypes was recorded. Similarly, hemolysis testing was conducted according to a published protocol for 3.5 L/min at 4000 RPM.[7]

Performance Comparison Using Regression Analysis

Once the hydraulic testing was completed, we quantitatively compared the pressure-flow performance of each stent configuration using a regression analysis. This method has been well described[9] and involves the calculation of nondimensional pressure and flow coefficients for the hydraulic data points. The statistical regression model generated characteristic

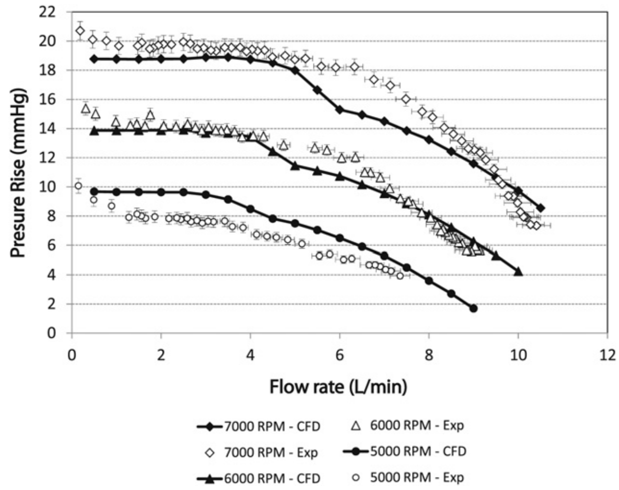


FIGURE 2. Comparison of the numeric predictions to the experimental measurements of the blood pump with a 4-bladed diffuser.

constants (β_0, β_1, β_2, and β_3), as described in the following equation, in which the subscript "type" indicates the pump prototype:

$$\psi_{TYPE} = \beta_3(\phi_{TYPE}^3)+\beta_2(\phi_{TYPE}^2)+\beta_1(\phi_{TYPE})+\beta_0 \quad (1)$$

The F test for regression analysis was used to assess the significance of the coefficients and polynomial models based on data normality and a preset α value of 0.05. This procedure was performed to compare the following regression models: (1) the numeric predictions and experimental measurements of the stent with 4 stationary diffuser blades, (2) the experimental performance of the stent without stationary diffuser blades with that of the stent with the stationary diffuser blades, (3) the experimental performance of all the stents compared with each other.

ET/BS

RESULTS

First Phase

Computational analysis of diffuser blades. Figure 2 demonstrates the pressure-flow performance curves from the numeric simulations of the 4-bladed diffuser configuration. These CFD predictions indicated that the pump generates 2 to 20 mm Hg of pressure for flow rates of 0.5 to 11 L/min at rotational speeds of 5000 to 7000 RPM. Within the expected operating flow range of 0.5 to 4 L/min, the numeric study predicted a constant head generation for the 5000 to 7000 RPM operating range. The predictions showed an increase in pressure generation as the number of diffuser blades on the stent increased.

In consideration of the risk of hemolysis and thrombosis, scalar stress estimations were performed for the models with the cage configurations. For 3.5 L/min at 6000 RPM, the model without diffuser blades had maximal stress levels of approximately 132 Pa, and 90% of the impeller and stent surfaces had fluid stresses less than 34 Pa. For the diffuser configuration, the maximal stress level was 178 Pa, and 85% of the impeller and stent surfaces remained less than 34 Pa. Greater fluid stress levels were predicted in regions in which the impeller blade tip was in closer proximity to the stent filaments.

Because the diffuser blades were designed to reduce the rotational flow component at the outlet of the pump, we examined the flow vorticity at 4 axial locations from the midspan of the diffuser blade into the outflow region. Figure 3 demonstrates a schematic of these axial and cross-sectional locations from the middle of the diffuser region into the outlet. A direct comparison of the flow vorticity at each location is provided for the stent model with and without diffuser blades. Figure 3, *B*, lists the average flow vorticity for each cross-sectional location for the 0-, 2-, 3-, 4-, and 5-bladed diffuser configurations. The 4-bladed diffuser configuration produced the lowest flow vorticity at each axial location and compared with the 0-, 2-, 3-, and 5-bladed geometries.

Experiments, regression models, and deviation. Figure 4 demonstrates the calculated pressure coefficients as a function of the flow coefficients for 2 cases: the CFD predictions of the pump model with a 4-bladed diffuser (CFD) compared with the experimental findings for the prototype with a 4-bladed diffuser; and the experimental findings for the prototype without diffuser blades compared with the prototype with a 4-bladed diffuser (Figure 2). The regression models for each data set were determined as follows:

$$\Psi_{\mathrm{CFD}} = 0.110(\Phi_{\mathrm{CFD}})^3-0.277(\Phi_{\mathrm{CFD}})^2 +0.050(\Phi_{\mathrm{CFD}})+0.074 \quad (2)$$

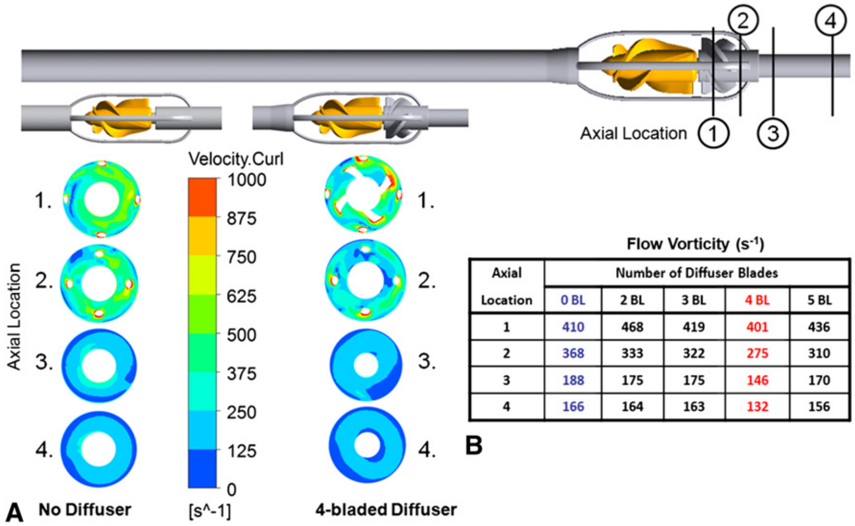
$$\Psi_{\mathrm{A}} = 0.248(\Phi_{\mathrm{A}})^3+0.204(\Phi_{\mathrm{A}})^2-0.122(\Phi_{\mathrm{A}})+0.054 \quad (3)$$

$$\Psi_{\mathrm{B}} = -0.473(\Phi_{\mathrm{B}})^3+0.240(\Phi)^2-0.077(\Phi_{\mathrm{B}})+0.081 \quad (4)$$

Normality for all data sets was found. The F test indicated a strong significance ($P < .001$) in the correlation of the polynomial trendlines to capture the trends of the experimental and CFD data. The correlation coefficients (R^2) and adjusted R^2 values were greater than 0.85 for the experimental data and greater than 0.99 for the CFD predictions. A Student *t* test indicated the significance for each of the coefficients in the regression models.

Second Phase

Experimental and hemolysis testing results of new stent filament designs. In addition to the 2 stent prototypes with straight filaments with and without diffuser blades, 9 new stent geometries with unique filament shapes were manufactured for testing. A similar quantitative comparison was performed by collapsing the experimental data into nondimensional coefficients. Figure 5 illustrates the graphed regression models for all the protective stents. The regression models for each data set determined from Figure 1 were as follows:



Axial Location	Number of Diffuser Blades				
	0 BL	2 BL	3 BL	4 BL	5 BL
1	410	468	419	401	436
2	368	333	322	275	310
3	188	175	175	146	170
4	166	164	163	132	156

FIGURE 3. Flow vorticity at 4 axial and cross-sectional locations from the diffuser to the outflow region. A direct comparison of the flow vorticity of the stent configuration with 4 diffuser blades to the configuration without diffuser blades was performed for 3.5 L/min at 6000 RPM. The average vorticity for each location was also predicted for each stent configuration with or without diffuser blades. The 4-bladed diffuser produced the lowest vorticity results compared with the other configurations.

$$\Psi_C = -0.242(\Phi_C)^3 - 0.017(\Phi_C)^2 - 0.063(\Phi_C) + 0.070 \quad (5)$$

$$\Psi_D = -1.655(\Phi_D)^3 + 0.613(\Phi_D)^2 - 0.077(\Phi_D) + 0.106 \quad (6)$$

$$\Psi_E = -1.658(\Phi_E)^3 + 0.168(\Phi_E)^2 - 0.063(\Phi_E) + 0.068 \quad (7)$$

$$\Psi_F = -0.970(\Phi_F)^3 + 0.550(\Phi_F)^2 - 0.209(\Phi_F) + 0.142 \quad (8)$$

$$\Psi_G = -1.558(\Phi_G)^3 + 0.535(\Phi_G)^2 - 0.103(\Phi_G) + 0.119 \quad (9)$$

$$\Psi_H = 0.541(\Phi_H)^3 - 0.788(\Phi_H)^2 + 0.064(\Phi_H) + 0.114 \quad (10)$$

$$\Psi_I = -1.44(\Phi_I)^3 + 0.381(\Phi_I)^2 - 0.067(\Phi_I) + 0.096 \quad (11)$$

$$\Psi_J = 0.290(\Phi_J)^3 - 0.176(\Phi_J)^2 - 0.077(\Phi_J) + 0.063 \quad (12)$$

$$\Psi_K = -0.945(\Phi_K)^3 + 0.875(\Phi_K)^2 - 0.385(\Phi_K) + 0.128 \quad (13)$$

Normality for all data sets was found, the F test also indicated strong significance ($P < .001$), and the t test supported each coefficient in the model. The correlation coefficients (R^2) and adjusted R^2 values were greater than 0.84 for the experimental data. The super diffuser geometry (ie, straight filaments and diffuser blades that were extended almost to the vessel wall) was able to further augment pressure by approximately 20 mm Hg compared with the protective stent with only straight filaments and no diffuser blade set. It was able to generate 2 to 32 mm Hg of pressure for flow rates of 0.5 to 4 L/min at rotational speeds of 5000 to 7000 RPM. Thus, we conducted hemolysis testing using this super-diffuser stent and the 3-bladed impeller configuration.

Hemolysis findings. During the blood bag experiments (n = 6) using the super diffuser stent, duplicate data measurements were performed for each sample interval. Variability in the rotational speed of the prototype, flow rate, and temperature of the loop was minimal during all experiments. The hematocrit levels remained at 36% to 40% with a small decline during the 6-hour period for all experiments. As would be expected, a linear increase in the plasma free hemoglobin (pfHb) concentration was found ($P < .001$). Per data normality, 1-way analysis of variance indicated that all the pfHb data had a strong dependence ($P < .001$) on time (in hours). The Tukey simultaneous analysis with pairwise comparison also demonstrated that the mean pfHb at each hourly interval was significantly different ($P < .001$) from the samples at other hours. The average and maximal normalized index of hemolysis level was 0.0056 g/100 L and 0.0064 g/100 L, respectively.

DISCUSSION

We focused our latest research on developing alternative therapies for patients with single ventricle physiology. The unique anatomic physiology of a single ventricle makes it

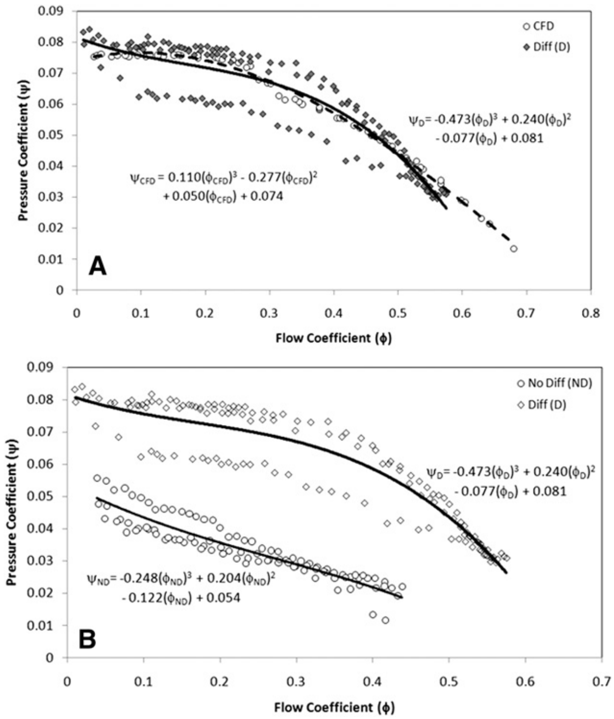


FIGURE 4. Regression analysis of the pressure and flow coefficients for each data set to facilitate a quantitative comparison of the results. A, Nondimensionalized hydraulic performance data of the numeric predictions of the stent configuration with a diffuser blade compared with the prototype testing. B, Nondimensionalized hydraulic performance data of the experimental testing of the stent configuration with and without the diffuser blade set.

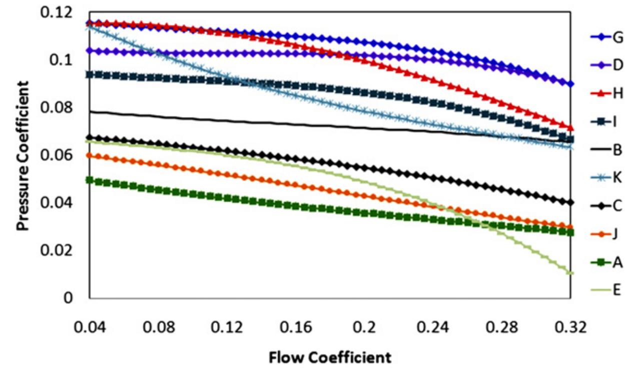


FIGURE 5. Comparison of the regression models of all the protective stent configurations evaluated in the present study.

an ideal environment for a blood pump with a distinctively designed protective stent. Chronic conditions, such as congestive heart failure, diminished exercise capacity, arrhythmias, and protein losing enteropathy, develop in most patients with single ventricle physiology as they age.[10] Few therapeutic options exist for these patients, as they decompensate toward heart failure. To address this need, we are developing an intravascular blood pump as a bridge-to-transplantation or bridge-to-hemodynamic stability for adolescents and adults with ailing single ventricle physiology.

Unique in design compared with other single ventricle blood pumps under development,[7,11,12] our device is a collapsible, percutaneously inserted, axial flow blood pump with a protective stent of filaments to prevent rotor touchdown within the vessel. Previous work has shown the feasibility of a 5-spindle protective stent design.[3,5] We explored the effect of an alternate cage geometry with a specially designed set of stationary diffuser blades that are mounted to the stent (first phase) and uniquely shaping the protective stent filaments (second phase). We speculated that stationary diffuser blades and new filament geometries would enhance energy transfer, enable operation at lower rotational speeds, and reduce the flow vorticity at the pump outlet.

During the numerical studies, we found that if a 5-bladed diffuser was used, much greater flow resistance occurred, and, thus, pressure generation was adversely affected. At the other end of the spectrum, we determined that the inclusion of too few diffuser blades (ie, <3) would limit the translation of kinetic energy to pressure and the removal of vorticity at the pump outlet. It is also not beneficial to select the 3-bladed diffuser configuration because the current impeller design also has 3 blades. Under conditions in which an identical blade number exists between a rotating impeller and a stationary diffuser region, it is possible that a harmonic effect in the fluid forces would occur because a perfect alignment of the blades relative to each region would happen more frequently during rotation.[9] This type of configuration is avoided to prevent the magnification of fluid forces and rotor instability that ensues. Finally, we determined that the 4-bladed diffuser resulted in the greatest removal of flow vorticity at the pump outlet, achieved a reasonable balance between pressure generation and flow resistance, and did not present an issue with identical blade numbers. Therefore, our future efforts will focus on the integration and optimization of the 4-bladed diffuser geometry.

The present study demonstrated that the pump with a stent with diffuser blades and straight filaments generates 2 to 20 mm Hg of pressure for flow rates of 0.5 to 4 L/min at rotational speeds of 5000 to 7000 RPM, thus meeting acceptable levels to support older patients with a single ventricle. The CFD predictions and experimental performance data for the prototype with a 4-bladed diffuser had averages that correlated within 16%, within expectations from the published data.[7,9] We determined that the prototype with the 4-bladed diffuser outperformed the prototype with no diffuser blades by an average deviation of 82% and a maximal difference of 118%. The CFD predictions indicated a ''stall'' characteristic that was not measured during prototype testing. This deviation could be attributed to using a commercial code for such complex fluid flow simulations. Overall, the presence of the

4-bladed diffuser blades functioned as designed by enhancing energy transfer. The scalar stress levels within the blood pump were also far less than the design criterion of 425 Pa for axial flow-assist devices.[13]

For a flow range of 0.5 to 4 L/min, all the stent configurations enhanced the transfer of energy from the rotating impeller compared with the straight filaments with no diffuser blades. We determined that the stent prototype with the tallest diffuser blades (super diffuser geometry) and straight filaments outperformed the stent with straight filaments and no diffuser region by an average of 180% and a maximum of 224%. It is expected that the protective stent will be flexible when constructed of nitinol material, including the diffuser blades, to avoid flow obstruction. The super diffuser stent was able to produce 2 to 32 mm Hg of pressure for flow rates of 0.5 to 4 L/min at rotational speeds of 5000 to 7000 RPM.

During the hemolysis experiments using the super diffuser stent, a linear and increasing trend of the pfHb concentration was found and met expectations.[14] The design objective for the maximum normalized index of hemolysis level for an adult left ventricular assist device during a support duration of 1 month is 0.01 g/100 L.[15] The axial flow pump with the super diffuser stent, as evaluated in the present study, demonstrated a maximum normalized index of hemolysis level of 0.0064 g/100 L. The present study represents a strong initial effort to develop an intravascular blood pump with a protective stent with uniquely shaped filaments and diffuser blades. The integration of these novel features onto protective stents could be broadly applied to all intravascular blood pumps with the benefits of improving flow control, lowering the operational RPM, reducing the risk of hemolysis and thrombosis, and enhancing energy transfer.

Although the results of the present study were encouraging, study limitations exist. Transient simulations would provide additional insight into the fluid dynamics in the pump, especially the fluid layers closest to the stent filaments. Although the 4-bladed impeller reduced the flow vorticity at the pump outlet, it did not eliminate the rotational component in the flow. Optimization of the diffuser geometry and blade angles will improve translation of energy and reduce the vorticity. Additional efforts will be made to also optimize the filament twist building on the present initial work.

CONCLUSIONS

We are developing a collapsible, percutaneously inserted, axial flow blood pump to support the cavopulmonary circulation in adolescent and adult patients with failing single ventricle physiology. This intravascular blood pump would serve as a bridge-to-transplantation or bridge-to-hemodynamic stability. The present study examined the integration of a stationary diffuser blade set onto a protective stent with uniquely designed filament geometries that serve to axially and radially stabilize the impeller and prevents rotor touchdown at the vessel wall. The findings of the present study have indicated that the stent geometry with straight filaments and diffuser blades that extend to the vessel or conduit diameter produced a pressure generation superior to that of the other evaluated stents. This super diffuser produced 2 to 32 mm Hg for flow rates of 0.5 to 4 L/min at 5000 to 7000 RPM. We determined that the prototype with the 4-bladed diffuser outperformed the prototype with no diffuser blades. The CFD predictions and experimental findings for the prototype with a 4-bladed diffuser correlated to within 16%. The diffuser blades also reduced the vorticity or rotational component of the flow as it exits the pump. Hemolysis testing using the super diffuser stent indicated acceptable levels. Our study represents a strong initial effort to develop an intravascular blood pump with a protective stent with uniquely shaped filaments and diffuser blades. The integration of these novel features onto protective stents could be broadly applied to all intravascular blood pumps with the benefits of improving flow control, lowering the operational rotational speed, reducing the risk of hemolysis and thrombosis, and enhancing energy transfer.

References

1. Olsen DB. The history of continuous-flow blood pumps. *Artif Organs*. 2000;24:401-4.
2. McCulloch B. Use of the Impella 2.5 in high-risk percutaneous coronary intervention. *Crit Care Nurse*. 2011;31:e1-6.
3. Throckmorton AL, Kishore RA. Design of a protective cage of filaments for an axial flow blood pump for intravascular cavopulmonary assist. *Artif Organs*. 2009;33:611-21.
4. Throckmorton AL, Kapadia JY, Carr JP, Powell CM, Tate RD, Traynham DV. Flexible impeller pump for intravascular cavopulmonary assistance of the Fontan physiology. *Cardiovasc Eng Technol*. 2011;1:244-55.
5. Kapadia JY, Pierce KC, Poupore AK, Throckmorton AL. Hydraulic testing of intravascular axial flow blood pump designs with a protective cage of filaments for mechanical cavopulmonary assist. *ASAIO J*. 2010;56:17-23.
6. Bhavsar SS, Moskowitz WB, Throckmorton AL. Interaction of an idealized cavopulmonary circulation with mechanical circulatory assist using an intravascular rotary blood pump. *Artif Organs*. 2010;34:816-27.
7. Throckmorton AL, Kapadia JY, Chopski SG, Bhavsar SS, Moskowitz WB, Gullquist SD, et al. Numerical, hydraulic, and hemolytic evaluation of an intravascular axial flow blood pump to mechanically support Fontan patients. *Ann Biomed Engr*. 2011;39:324-36.
8. Bludszuweit C. Three-dimensional numerical prediction of stress loading of blood particles in a centrifugal pump. *Artif Organs*. 1995;19:590-6.
9. Throckmorton AL, Untaroiu A, Allaire PE, Wood HG, Lim DS, McCulloch MA, et al. Numerical design and experimental hydraulic testing of an axial flow VAD for infants and children. *ASAIO J*. 2007;53:754-61.
10. Ravishankar C, Gaynor JW. Mechanical support of the functionally single ventricle. *Cardiol Young*. 2006;16:55-60.
11. Lacour-Gayet FG, Lanning CJ, Stoica S, Wang R, Rech BA, Goldberg S, et al. An artificial right ventricle for failing Fontan: in vitro and computational study. *Ann Thorac Surg*. 2009;88:170-6.
12. Rodefeld MD, Coats B, Fisher T, Gridharan GA, Chen J, Brown JW, et al. Cavopulmonary assist for the univentricular Fontan circulation: von Karman viscous impeller pump. *J Thorac Cardiovasc Surg*. 2010;140:529-36.
13. Paul R, Apel J, Klaus S, Schugner F, Schwindke P, Reul H. Shear stress related blood damage in laminar Couette flow. *Artif Organs*. 2003;27:517-29.
14. Mueller MR, Schima H, Engelhardt H, Salat A, Olsen DB, Losert U, et al. In vitro hematological testing of rotary blood pumps: remarks on standardization and data interpretation. *Artif Organs*. 1993;7:103-10.
15. Nosé Y. Design and development strategy for the rotary blood pump. *Artif Organs*. 1998;22:438-46.

ET/BS